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Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98N-0359, Program Priorities in the Center for Food safety and Applied Nutrition; Request for Comments

I am pleased to offer comments on behalf of the Association of Food and Drug Officials (AFDO). AFDO is a 105 year old non-profit, professional association comprised of "regular," voting members who are state, federal, and local regulator officials and non-voting, "associate" members who are employed with or affiliated with the food, drug, medical device or cosmetic industries.

AFDO's comments attempt to reflect the focus stated by FDA's Center for Food Safety and Applied Nutrition in proposing its priorities for 2001, "Where do we do the most good for consumers?" The overall tone of our comments also is intended to reinforce the need and value of integrating federal, state, and local resources in addressing key food safety and consumer protection issues. To assist you in reviewing these comments we have organized them into the structure of CFSAN's 2000 Program Priorities. Comments about additional subjects are listed at the end.

Strategy 1.2 – Risk Management

- ❖ Egg Safety. Publish the final rule on labeling and refrigeration of eggs at retail.

We believe there is value in establishing a single, uniform temperature requirement for eggs throughout processing and distribution channels. Establishing a uniform temperature would clarify expectations for the industry, regulators, and consumers.

- ❖ Imports. In conjunction with the U.S. Customs Service, implement the President's directives to prevent the importation of unsafe food.

Though all of the activities listed under this heading have value, the "bang for the buck" is contained in the five actions listed under this heading. Monitoring provides baseline information and working toward greater equivalency with foreign nations is a valuable long-term goal, but the immediate need is to strengthen the system for monitoring the safety of imported foods at the port of entry.

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- ❖ We also recommend that FDA consider expanding import partnerships in states where high volume ports of entry are located.
- ❖ Juice HACCP. Publish a final rule regarding HACCP for fruit and vegetable juices to improve their safety.
- ❖ Food Code. Work with the Conference of Food Protection to resolve controversial Food Code issues remaining after the 2000 Conference and achieve adoption of the Food Code by 35% of states.

Both of these actions necessary and possible. There are still a precious few nagging controversial issues. We urge CFSAN to work with the CFP and key constituencies to negotiate resolution to these outstanding issues. Good public health policy should be the primary objective, but good common sense and practicality should be incorporated whenever possible.

- ❖ Support for the National Food Safety System Outbreak Coordination Workgroup. In collaboration with ORA, and state and local governments, continue to provide support for the National Food Safety System Outbreak Coordination Workgroup project to develop guidelines for coordinating multi-state outbreaks and tracebacks.

Development of a more cooperative and coordinated outbreak response and traceback system is a key component in the overall effort to integrate this nation's food safety system.

Strategy 1.3 – Risk Assessment and Risk Identification

- ❖ Risk assessments for *Listeria monocytogenes* and *Vibio parahaemolyticus*. Complete development of risk assessments for *Listeria monocytogenes* and *Vibio parahaemolyticus*.

Both risk assessments must be finalized to provide science-based guidance to food businesses and food regulators. Industries need to have science-based operational guidance, regulators need to be able to set science-based priorities for monitoring and follow-up, and consumers need to be assured that operational and regulatory guidance does not compromise food safety.

- ❖ Identification of New assessment needs.

Though day-to-day events can keep the plate continually full, it is essential that efforts such as this to forecast and assess risks associated with specific pathogens, contaminants, or commodities in proactive rather than a reactive way. It's a "pay me now or pay me much more later" proposition. It should be a priority to make proactive risk assessment a priority.

- ❖ Harmonize standards for *E. coli* 0157:H7
- ❖ We support continuation and completion this effort to standardize sampling and analytical methods and to improve data exchange. However, harmonization of

standards and improvement in the data sharing system for this organism are only the experimental template. The larger value of this project will occur when improvements to the underlying processes for standardization of data and the newly created system to share the data are applied more broadly.

Strategy 1.4 – Risk communication

- ❖ Though all of the actions listed in this section of the current “A” list would be valuable, it may pay to narrow the focus to make completion feasible in a 12 month workplan. Egg safety, fruit and vegetable juices, and Good Agricultural Practices seem like the top candidates for immediate education and outreach efforts.

Strategy 2.1 – Premarket Review of Food and Color Additives and Food Ingredients

- ❖ Simultaneous review of food ingredients in meat and poultry

Strategy 2.3 – Dietary Supplements

- ❖ In the interest of bringing even greater focus to the work plan, the actions listed under the following headings are the most essential from our perspective.
 - Safety issues
 - Good Manufacturing Practices
 - Structure and function claims
 - Claims
- ❖ As a new item under this heading, we recommend that CFSAN work with the states via AFDO to address the following dietary supplement-related issues.
 - Determine which supplements present documented the most serious and repetitive safety risks and develop a cooperative strategy to decrease the safety risk.
 - Further clarify issues involving boundaries between:
 - Supplements in conventional food form
 - Conventional foods improperly marketed as supplements
 - Structure/function claims versus unapproved drug claims.
 - Clarify labeling issues about structure and function claims, supplement/food claims, and label claims associated with active ingredient levels.
 - Complete and publish GMPs for Supplements.

Strategy 3.3 – International

- ❖ Publish equivalence criteria
- ❖ For those nations that have or are capable of developing a food safety system equivalent to that of the United States, this is a key step toward assuring the safety of imported products.

Strategy 3.4 – Emerging Areas

❖ Food allergens

There has been a significant effort to increase consumer and industry awareness about allergens, the actions outlined need stay near the top of the list

❖ Adverse event reporting

Integration of this information is crucial for effective risk assessment and risk communication as well as for the development of effective regulatory strategies.

Strategy 3.5 – Regulatory Processes

❖ All of the actions listed under this section are critical and should remain on the “A” list.

Additional Comments

❖ Universal HACCP

FDA should continue to explore the idea of adopting a “Universal HACCP” regulation. Currently, HACCP is being developed using a commodity-based approach that is frequently reactive rather than strategic. We urge the development of a comprehensive strategy and plan for developing and implementing HACCP or other appropriate risk-based approach across the entire food safety system.

❖ National Food Safety System project support

This project continues to hold the promise of great good. There are several initiatives underway to transform good ideas and promises into real life improvements, but as normally happens when an idea is moved from the drawing board to the street, it’s a lot more difficult, time consuming, and expensive than it looked in the drawing room. The NFSS project has benefited greatly from the support provided by CFSAN. We recommend that support of this effort to integrate the food safety system remain near the top of the “A” list.

❖ Training

Training is a foundation element for building the equivalency needed to develop and sustain an integrated food safety system. We encourage CFSAN to work closely with ORA to develop, deliver, and fund training necessary to assure that state and local food safety staffs have at least equivalent knowledge and skills.

On behalf of AFDO, I thank you for this opportunity to provide input about CFSAN’s 2001 priorities.

Sincerely,

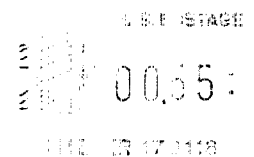


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